

REMARKS

The Examiner has withdrawn the rejection of claims 1-10 for obviousness-type double patenting, over commonly assigned U.S. Patent No. 7,070,768 in view of U.S. Patent No. 5,290,562, in view of the Terminal Disclaimer filed with the last amendment. The applicants thank the Examiner for this action.

The Examiner has rejected claim 11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for converting gray hair to the original pigment in the hair follicle of a subject being treated by the instant composition, does not reasonably provide enablement for preventing graying of hair. This rejection is believed to be incorrect for the reasons previously stated in the last amendment. However, to promote the prosecution of the present application, applicant has cancelled this claim and will pursue a patent on the subject matter of claim 11 in a separate continuation of the present patent application.

The Examiner has withdrawn the rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,262,105 (Johnstone). Again, the applicant thanks the Examiner for this action.

However, the Examiner has now rejected all of the claims under 35 U.S.C. 103(a) as unpatentable over the article New Drugs of 2001 (J. Amer. Pharm. Association 2002), hereinafter the "Article", itself, or in view of Ortonne et al (Pigmentation of Hair), hereinafter "Ortonne". The Article teaches that "bimatoprost is useful in reducing intraocular pressure.... However, the side effects of the compound included among others, darkening of the eyelashes, eyelash growth and pigmentation" The Examiner agrees that the Article fails to teach the claimed method, *per se*, but argues that one of ordinary skill in the art would have found it obvious to use bimatoprost for increasing pigmentation or darkening of eyelashes because bimatoprost and, in general, prostaglandins are known to increase pigmentation of skin and hair by increasing the number of

melanosomes.

It is again pointed out to the Examiner that bimatoprost is not a prostaglandin. (See the arguments that were presented in the previous amendment and the paper by Woodward which paper-- it is believed-- persuaded the Examiner to withdraw the rejection for obviousness over the prostaglandin-based method of Johnstone.)

Because bimatoprost is not a prostaglandin, it is clear that the Article cited by the Examiner would not lead one of ordinary skill in the art to the conclusion that bimatoprost could convert grey hair to its original color.

Moreover, the Article also reports that only 3-10% of the patients treated with any of "the prostaglandin-type agents"—and as pointed out above, bimatoprost is not a prostaglandin—had "eyelash darkening."

Since bimatoprost is not a prostaglandin and since only 3-10% of the patients treated with **prostaglandins** showed eyelash darkening, it is believed that the Article, by itself does not render the claimed invention obvious.

The Examiner has combined Ortonne in an attempt to cure the deficiencies in the Article.

Ortonne discloses that the concentration and type of melanin pigments cause the various colors in hair. Ortonne also discloses that the absence of pigment results in grey hair. But Ortonne does not disclose any method or compound to convert grey hair back to its natural color. Thus, since the Article does not teach the bimatoprost (or any other compound) would convert grey hair back to its natural color, the combination of the Article and Ortonne also fails.

To further distinguish the claimed invention from the prior art, and without any admission or abandonment of any of the embodiments of the invention, applicant has amended the claims to point out that the method of the invention is primarily directed toward the treatment of grey hair of the

scalp or beard of a human. This limitation further distinguishes the invention, as claimed, from the Article, which, as discussed above, discloses the changes in eyelashes only. (Note the applicant hereby offers the following articles to point out that eyelashes are not equivalent to scalp hair:

Hormone Research 2000;54:243-250

This article points out that androgens transform unpigmented vellus hairs to terminal pigmented hairs but have no effect on eyelashes.)

Hair Science: How and Why Hair Grows

This article points out the difference between scalp hair and facial hair. Cf. new claims 15-17.

Support for this amendment is found at lines 15-18 of page 7; lines 18-20 of page 8; and line 20 of page 9, as well as Examples 2 and 3. The new claims 12-17 also further distinguish the claimed invention and are supported by the Examples and at page 9, lines 26-30.

Thus, in view of the failure of the Article to suggest that bimatoprost would convert grey hair to its original color and since Ortonne does not suggest the use of any compound to convert grey hair to its original color, it is believed that neither the Article, alone, nor the further inclusion of Ortonne makes the invention, as claimed, obvious under 35 USC 103(a).

Thus, it is believed that the claims, as presently amended, are in condition for allowance. The Examiner is asked to reconsider and withdraw his rejection and pass the claims to issue.

Respectfully submitted,



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